MR#338029

September 7, 2011

Contains TSCA Confidential Business
Information within brackets {}
Sanitized Copy

TSCA Confidential Business Information Center (7407M)
EPA East – Room 6428 Attn: Section 8(e)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Subject: Notice in Accordance with TSCA Section 8(e): Results of a Toxicity Study: [preliminary prenatal developmental toxicity study in rabbits] with { }

Dear Sir/Madam,

{}, submits this letter under section 8(e) of the Toxic Substances Control Act (TSCA) to inform the U.S. Environmental Protection Agency (EPA) of the results of toxicity testing with an early stage experimental pesticide being screened for potential registration and development in the United States.

The subject study was conducted with { }, no CAS No. available. Details of the study are attached.

{ } understands that reporting of results from this study under TSCA 8(e) is in accordance with EPA's policy. { } has not made a determination at this time that any substantial risk of injury to human health or the environment is presented by the findings within the subject study.

Please note that a confidential version of this letter is enclosed, treating the chemical identity and company identity as Confidential Business Information.

A Confidentiality Substantiation Questionnaire is being submitted for the substance.

If you have any questions with regard to this submission, please contact me at {}.

Sincerely,
{ }

Company Sanitized

Attachments

Prenatal developmental toxicity study in rabbits with _____

(Preliminary study)

The following results should be reported in compliance with TSCA Section 8(e).

(1) In maternal animals, decreased body weight gain and suppressed food consumption were observed at the dosage of 12.5 mg/kg and above. Therefore, the NOEL of this study was less than 12.5 mg/kg (In the case of oral toxicity study with the shorter dosing period than 4 weeks, it is reportable when NOEL is below 200 mg/kg).

(2) Abortion or premature delivery, considered to be caused by suppression of food consumption, was observed at 50 mg/kg and above (Biologically or statistically significant alteration in number of animals that aborted or prematurely delivered are reportable.)

(3) Embryo-fetal mortality tended to be increased, and fetal body weight tended to be low at 100 mg/kg (Biologically or statistically significant changes on embryo-fetal mortality and fetal body weight are reportable.).

(4) In fetuses, in 100 mg/kg, skeletal malformations (nodulated ribs) was observed in a few fetuses and increased tendency of skeletal variations, such as incomplete ossification of hyoid bone and unossified pubis. Additionally, decreased tendency of number of ossified middle phalanges of finger, which is indicator of skeletal ossification, were observed at 100 mg/kg (Biologically or statistically significant alterations in skeletal malformations/ variations and skeletal ossifications are reportable.).

Comments

Study methods:

Animals; Kbl:NZW rabbit, 5 artificially-inseminated animals/group

Dosage level; 12.5, 25, 50 and 100 mg/kg

Administration route; by gavage (vehicle: 0.5% MC)

Treatment period; days 6-27 of gestation (caesarean section; day 28 of gestation)

Results

In maternal animals, decreased body weight gain and suppressed food consumption were observed at 12.5 mg/kg and above. Also, abortion or premature delivery, considered to be caused by suppressed food consumption, was observed at 50 mg/kg and above.

In fetuses, increased tendency of embryo-fetal mortality and decreased tendency of fetal body weight were observed at 100 mg/kg. A few skeletal malformations (nodulated ribs) were observed and the skeletal variations, such as incomplete ossification of hyoid bone and unossified pubis, tended to increase at 100 mg/kg. Furthermore, number of ossified middle phalanges of fingers tended to decrease in female fetuses.